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FRONT

Package leaflet: Information for the user

Oxytocin 10 IU/ml Solution for infusion

Oxytocin

Read all of this leaflet carefully before you receive this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, midwife or pharmacist.
- If you get any side effects, talk to your doctor, midwife or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Oxytocin is and what it is used for
2. What you need to know before you receive Oxytocin
3. How Oxytocin is given to you
4. Possible side effects
5. How to store Oxytocin
6. Contents of the pack and other information

1. What Oxytocin is and what it is used for

Oxytocin 10 IU/ml Solution for infusion contains a manufactured form of oxytocin (a natural hormone). It belongs to a group of medicines called oxytocics that makes the muscles of the womb contract.

Oxytocin is used:
- to start or help contractions during childbirth (labour);
- to help in the management of a miscarriage;
- during a caesarean section;
- to prevent and control bleeding after delivery of your baby.

2. What you need to know before you receive Oxytocin

You must not receive Oxytocin:
- if you are allergic to oxytocin or any of the other ingredients of this medicine (listed in section 6);
- if your doctor thinks that to start or increase contractions of the womb would be unsuitable for you, for example:
  - where contractions of the womb are unusually strong;
  - where there are obstructions that may prevent delivery;
  - where your baby may be short of oxygen;
- where labour or vaginal delivery is not advisable, for example:
  - if your baby's head is too large to fit through your pelvis;
  - if your baby is wrongly positioned in the birth canal;
  - if the placenta lies near or over the neck of your womb;
  - if your baby lacks oxygen due to blood vessels running across the neck of your womb;
  - if the placenta separates from the womb before the baby is born;
  - if there are one or more loops of umbilical cord between the baby and the neck of the womb, either before or after your waters break;
  - if your womb is over-extended and more likely to tear, for example if you are carrying more than one baby or have too much water (amniotic fluid) in your womb;
  - if you have had five or more pregnancies in the past or if your womb is scarred by previous caesarean section or other surgery;
- if you have been given medicines called prostaglandins (used to bring on labour or treat stomach ulcers). Oxytocin should not be used for 6 hours after vaginal prostaglandins as the effects of both medicines may be increased.

Oxytocin should not be used for prolonged periods if:
- your contractions do not increase with the treatment;
- you have a condition known as severe pre-eclamptic toxaemia (high blood pressure, protein in the urine and swelling);
- you have severe problems with your heart or blood circulation.

Warnings and precautions
Oxytocin should only be administered by a healthcare professional in a hospital setting.

Oxytocin should not be given as rapid injection into a vein as this may cause decreased blood pressure, a sudden brief sensation of heat (often over the entire body), and an increased heart rate.

Talk to your doctor or midwife before you receive Oxytocin if:
- you are prone to chest pain due to pre-existing heart and/or circulation problems;
- you have a known irregular heart beat ('long QT syndrome') or related symptoms, or are taking medicines known to cause the syndrome (see section 'Other medicines and Oxytocin');
- you have had a previous caesarean section;
- you are more than 35 years old;
- you have raised blood pressure or heart problems;
- your womb was contracting strongly but has now begun to contract less strongly;
- you have been told by a doctor or midwife that normal delivery may be difficult for you due to the small size of your pelvis;
- you have kidney problems, as Oxytocin can cause water retention;
- you have had complications during your pregnancy;
- you are more than 40 weeks pregnant.

When Oxytocin is given to induce and enhance labour, the infusion rate should be set to maintain a contraction pattern similar to normal labour and adjusted to individual response. Too high doses may cause very strong continuous contractions and possibly tearing of the womb, with serious complications for you and your baby.

Oxytocin may rarely cause disseminated intravascular coagulation which causes symptoms including abnormal blood clotting, bleeding and anaemia.
High doses of Oxytocin may force amniotic fluid from your womb into your blood. This is known as amniotic fluid embolism.

Large doses of Oxytocin over a long period of time, whilst drinking or receiving large volumes of fluid may make your stomach feel very full, cause difficulty in breathing and lower salt levels in your blood.

If any of the above applies to you, or if you are not sure, speak to your doctor or midwife before you receive Oxytocin.

Latex allergy
The active substance in Oxytocin 10 IU/ml Solution for infusion might cause a severe allergic reaction (anaphylaxis) in patients with latex allergy. Please tell your doctor if you know you are allergic to latex.

Children and adolescents
Oxytocin is not intended for use in children or adolescents.

Other medicines and Oxytocin
Tell your doctor or midwife if you are taking or have recently taken any of the following medicines as they may interfere with Oxytocin:
- prostaglandins (used to start labour or to treat stomach ulcers) and similar drugs as the effects of both drugs may be increased;
- medicines that can cause an irregular heartbeat, as Oxytocin may increase this effect;
- anaesthetics which you breath in (e.g. to put you to sleep during surgery), such as halothane, cyclopropane, sevoflurane or desflurane), as these may weaken your contractions, or cause problems with your heartbeat;
- anaesthetic medicines for local or regional pain relief, in particular an epidural for pain relief during labour. Oxytocin may increase the blood vessel narrowing effect of these medicines and cause an increase in blood pressure.

Please tell your doctor or midwife if you are taking, have recently taken or might take any other medicines.

Oxytocin with food and drink
You may be told to keep the amount of fluids you drink to a minimum.

Pregnancy, breastfeeding and fertility
Based on the wide experience of use and the nature of this medicine, it is not expected that Oxytocin would be a risk to your baby when used correctly.
Oxytocin may be found in small amounts in breast milk, but is not expected to have harmful effects because it is quickly inactivated by your baby's digestive system.
The effects of oxytocin on fertility are unknown.

Driving and using machines
Oxytocin can start labour. Women with uterine contractions should not drive or use machines.

Oxytocin contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per 1 ml ampoule, i.e. essentially 'sodium-free'.

The following information is intended for healthcare professionals only:

Oxytocin 10 IU/ml Solution for infusion

Indication	Method of administration
Induction or enhancement of labour	Oxytocin should not be started for 6 hours following administration of vaginal prostaglandins. Oxytocin should be administered as an intravenous (i.v.) drip infusion or, preferably, by means of a variable-speed infusion pump. For drip infusion it is recommended that 5 IU (8.3 micrograms) of Oxytocin be added to 500 ml of a physiological electrolyte solution (such as sodium chloride 0.9 %). For patients in whom infusion of sodium chloride must be avoided, 5 % dextrose solution may be used as the diluent. To ensure even mixing, the bottle or bag must be turned upside down several times before use. The initial infusion rate should be set at 2 to 8 drops/minute (1 to 4 milliunits/minute). It may be gradually increased at intervals not shorter than 20 minutes and increments of not more than 1 to 2 milliunits/minute, until a contraction pattern similar to that of normal labour is established. In pregnancy near term this can often be achieved with an infusion of less than 20 drops/minute (10 milliunits/minute), and the recommended maximum rate is 40 drops/minute (20 milliunits/minute). In the unusual event that higher rates are required, as may occur in the management of foetal death in utero or for induction of labour at an earlier stage of pregnancy, when the uterus is less sensitive to oxytocin, it is advisable to use a more concentrated oxytocin solution, e.g., 10 IU (16.7 micrograms) in 500 ml. When using a motor-driven infusion pump which delivers smaller volumes than those given by drip infusion, the concentration suitable for infusion within the recommended dosage range must be calculated according to the specifications of the pump. The frequency, strength and duration of contractions as well as the foetal heart rate must be carefully monitored throughout the infusion. Once an adequate level of uterine activity is attained, aiming for 3 to 4 contractions every 10 minutes, the infusion rate can often be reduced. In the event of uterine hyperactivity and/or foetal distress, the infusion must be discontinued immediately. If, in women who are at term or near term, regular contractions are not established after the infusion of a total amount of 5 IU (8.3 micrograms), it is recommended that the attempt to induce labour be ceased; it may be repeated on the following day, starting again from a rate of 2 to 8 drops/minute (1 to 4 milliunits/minute).
Incomplete, inevitable or missed abortion	5 IU (8.3 micrograms) by i.v. infusion (5 IU diluted in physiological electrolyte solution and administered as an i.v. drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes), if necessary followed by i.v. infusion at a rate of 20 to 40 milliunits/minute.

3. How Oxytocin is given to you

Oxytocin should only be given under medical supervision and in a hospital.
Your doctor or midwife will decide when and how to treat you with Oxytocin. If you think that the effect of Oxytocin is too strong or too weak, tell your doctor or midwife. While you are receiving Oxytocin, both you and your baby will be closely monitored.

Oxytocin is usually diluted before use and given as an intravenous infusion (drip) into one of your veins.

The usual dose is different in the following circumstances:

To start or help contractions during labour: The rate of infusion will start at 2 to 8 drops per minute. This may be gradually increased to a maximum rate of 40 drops per minute. The infusion rate can often be reduced once the contractions reach an adequate level, about 3 to 4 contractions every 10 minutes.
If your contractions do not reach the adequate level after 5 IU (8.3 micrograms), the attempt to start labour should be stopped and then repeated the following day.

Miscarriage: The dose is 5 IU (8.3 micrograms) by infusion into a vein. In some cases this may be followed by a drip at 40 to 80 drops per minute.

Caesarean section: The dose is 5 IU (8.3 micrograms) by infusion into a vein immediately after delivery of your baby.

Prevention of bleeding after delivery: The dose is 5 IU (8.3 micrograms) by infusion into a vein after delivery of the placenta.

Treatment of bleeding after delivery: The dose is 5 IU (8.3 micrograms) by infusion into a vein. In some cases this may be followed by a drip containing 5 to 20 IU (8.3 to 33.4 micrograms) of oxytocin.

Older people (65 years and over): Oxytocin is not intended for use in elderly.

Patients with kidney disease: There is no information on use in patients with kidney disease. However, you should tell your doctor if you suffer from kidney problems (see section 2).

Patients with liver disease: There is no information on use in patients with liver disease.

If you receive more Oxytocin than you should
As this medicine is given to you in hospital, it is very unlikely that you will receive an overdose.
If anyone accidentally receives this medicine, tell the hospital accident and emergency department or a doctor immediately. Show any left over medicines or the empty packet to the doctor.

An overdose of Oxytocin could cause:
- very strong contractions of your womb;
- damage to your womb which could include tearing;
- the placenta to come away from your womb;
- amniotic fluid (the fluid around the baby) to enter your bloodstream;
- harm to your baby.

If you miss a dose of Oxytocin
As a doctor or midwife is giving you this medicine, you are unlikely to miss a dose.
If you have any further questions on the use of this medicine, ask your doctor or midwife.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (affects more than 1 in 100 patients)
- Headache
- Fast or slow heartbeat
- Feeling or being sick

Uncommon side effects (affects more than 1 in 1,000 patients)
- An irregular heartbeat

Rare side effects (affects more than 1 in 10,000 patients)
- A severe allergic reaction with difficulty in breathing, dizziness and light-headedness, feeling faint, nausea, cold and clammy skin or a fast or weak pulse
- Rash

Other side effects

Effects in the mother:
Not known (cannot be estimated from the available data)
- Chest pain (angina)
- Irregular heartbeat (QTc prolongation seen on electrocardiogram)
- Low blood pressure
- Haemorrhage (bleeding)
- Increased uterine tone
- Excessive or continuous contractions
- Tearing of the womb
- Fluid retention (water intoxication). Symptoms may include headache, anorexia (loss of appetite), feeling or being sick, stomach pain, sluggishness, drowsiness, unconsciousness, low levels of certain chemicals in the blood (e.g. sodium or potassium), fits
- Low blood salt levels
- Sudden fluid overload in the lungs
- Sudden brief sensation of heat often over the whole body
- Abnormal blood clotting, bleeding and anaemia (disseminated intravascular coagulation)

Effects in the baby:
Not known (cannot be estimated from the available data)
Excessive contractions may cause:
- Shortage of oxygen, suffocation and death
- Low blood salt levels

Reporting of side effects
If you get any side effects, talk to your doctor or midwife. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store Oxytocin

Keep this medicine out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Keep the ampoules in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxytocin contains
The active substance is oxytocin.
Each ml of solution contains 10 IU (16.7 micrograms) oxytocin.

The other ingredients are: acetic acid, glacial; sodium acetate trihydrate; sodium chloride; sodium hydroxide; water for injections.

What Oxytocin looks like and contents of the pack
Colourless, clear liquid with characteristic odour.
Transparent 1 ml type 1 glass ampoules.
Pack sizes:
5 ampoules
10 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Esteve Pharmaceuticals Ltd,
The Courtyard Barns, Choke Lane,
Cookham Dean, Maidenhead,
Berks, SL6 6PT, United Kingdom

Manufacturer
AS GRINDEKS.
Krustpils iela 53, Rīga, LV-1057, Latvia

For any information about this medicine, please contact the Marketing Authorisation Holder.

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Caesarean section	5 IU (8.3 micrograms) by i.v. infusion (5 IU diluted in physiological electrolyte solution and administered as an i.v. drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) immediately after delivery.
Prevention of postpartum uterine haemorrhage	The usual dose is 5 IU (8.3 micrograms) by i.v. infusion (5 IU diluted in physiological electrolyte solution and administered as an i.v. drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes) after delivery of the placenta. In women given oxytocin for induction or enhancement of labour, the infusion should be continued at an increased rate during the third stage of labour and for the next few hours thereafter.
Treatment of postpartum uterine haemorrhage	5 IU (8.3 micrograms) by i.v. infusion (5 IU diluted in physiological electrolyte solution and administered as an i.v. drip infusion or, preferably, by means of a variable-speed infusion pump over 5 minutes), followed in severe cases by i.v. infusion of a solution containing 5 to 20 IU (8.3 to 33.4 micrograms) of oxytocin in 500 ml of an electrolyte-containing diluent, run at the rate necessary to control uterine atony.

Paediatric population: There are no indications for use of Oxytocin in children or adolescents.

Older people (65 years and over): There are no indications for use of Oxytocin in elderly.

Route of administration: Intravenous infusion.

Incompatibilities: Oxytocin should not be infused via the same apparatus as blood or plasma, because the peptide linkages are rapidly inactivated by oxytocin-inactivating enzymes. Oxytocin is incompatible with solutions containing sodium metabisulphite as a stabiliser.

Excipients: Each 1 ml ampoule contains 2.99 mg (0.13 mmol) sodium. This medicinal product contains less than 1 mmol sodium (23 mg) per 1 ml ampoule, i.e. essentially 'sodium-free'.

Instructions on preparation and dilution: Oxytocin is compatible with the following infusion fluids: sodium chloride 0.9 %, dextrose 5 %, Ringer's solution, acetated Ringer's solution.

For drip infusion it is recommended that 5 IU (8.3 micrograms) of Oxytocin be added to 500 ml of a physiological electrolyte solution (such as sodium chloride 0.9 %). For patients in whom infusion of sodium chloride must be avoided, 5 % dextrose solution may be used as the diluent. To ensure even mixing, the bottle or bag must be turned upside down several times before use.

Storage: Store in a refrigerator (2 °C − 8 °C). Keep the ampoules in the outer carton in order to protect from light.
Storage of diluted product: see 'Shelf life' below.

Shelf life: 4 years.
Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C when diluted with the solutions stated in subsection 'Instructions on preparation and dilution' above. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.